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- 1.0

PURPOSE

Cardinal Health QRA Anti-Diversion uses this procedure to evaluate individual customer's controlled substances and list 1 chemicals threshold events; arrive at a decision, document, and communicate threshold event decisions.
- 2.0

SCOPE

All Pharmaceutical Operations and Customers, Quality and Regulatory Affairs, Supply Chain Integrity.
- 3.0

INCLUDED ATTACHMENTS AND FORMS

None
- 4.0

POLICY
- 4.1

Definitions

Threshold Event

An order for a regulated drug which exceeds the threshold set for a specific licensed customer.

DEA Limit Over Threshold Report

A report generated by members of IT containing all threshold events from a specified date.

Distrack Held Order Report

A report generated by QRA containing all current orders held as a result of the customer's accrual for a drug family exceeding the assigned QRA threshold limit.

Anti-Diversion Customer Profile

A report generated by QRA containing various background, licensing, and analytical metrics relevant to a customer used to assist in the evaluation of threshold events.

Applied Reasoning

The use of concrete data and technical information to resolve a problem and make a decision by placing knowledge and thinking into practice or to a specific use. Skills include basic understanding of cause and effect, and a concrete primary knowledge base not involving complex analysis or theory. Applied reasoning is used in physics, medicine, technology, etc.
- 4.2

Procedures

Review Anti-Diversion Customer Profile for: (see example below)

1. Drug Family Threshold Event

2. Customer Type

3. Distributor Information (primary vs secondary)

4. Total number of threshold events for customer

5. Total number of threshold events for this drug family for customer

6. Monthly drug family usage

7. Total current monthly accrual

8. Monthly drug family limit



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4.2.1

Anti-Diversion Customer Profile Screen Print.

Enlarged area of Customer Profile Screen Print containing Distrack Information.

(To review a held order in Distrack, use the Distrack Information Box on the Anti-Diversion Customer Profile to locate the appropriate distribution center region, actual distribution center, customer account number and drug family code) See Screen Print above.

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4.2.2

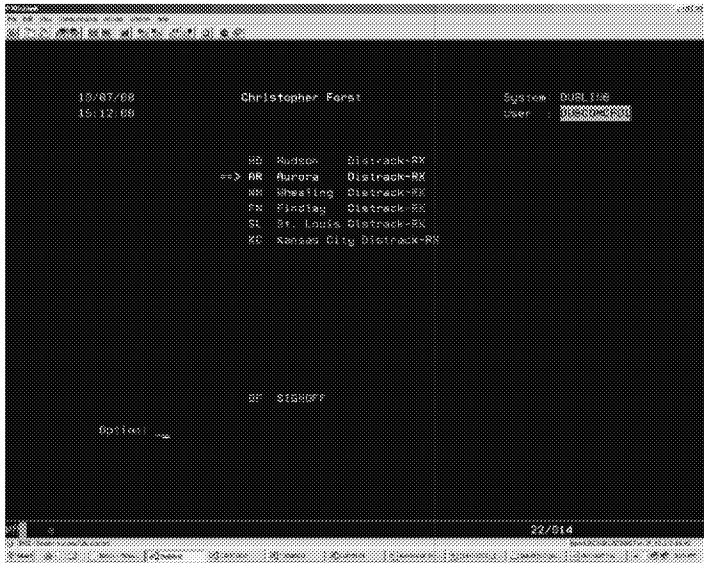


Figure SEQ Figure * ARABIC

Initial sign-on screen for Dublin 6 (HYPERLINK \ "Figure1")

This screen shows distribution centers located in Dublin 6 region.

Under Option type distribution center where held order is located.

Pressing Enter opens the DEA Operations Menu. (HYPERLINK \ "Figure2")



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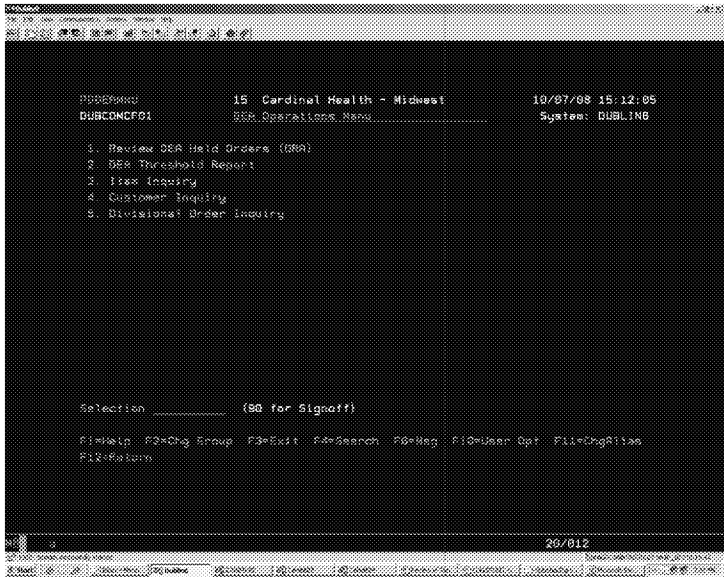
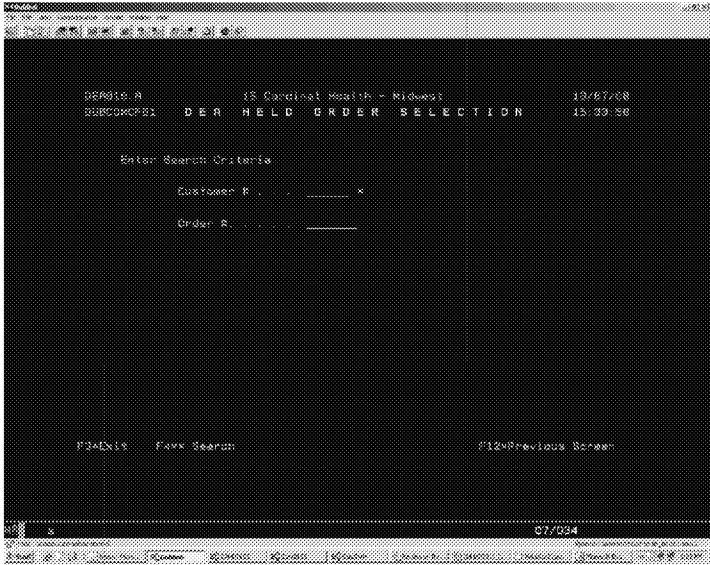


Figure [SEQ Figure * ARABIC] [{ - SEQ Figure * ARABIC - }

To view a DEA Held Order on this screen ([HYPERLINK \ \ "Figure2"] [{ - HYPERLINK \ \ "Figure2" - }]), enter 1 on Selection Line.

Pressing Enter opens the DEA Held Order Selection Screen. ([HYPERLINK \ \ "Figure3"] [{ - HYPERLINK \ \ "Figure3" - }])

Enter the Customers account number on the Customer # line (or held order number if available).



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Figure [SEQ Figure * ARABIC]({ SEQ Figure * ARABIC })

Pressing Enter opens the next screen which lists the held order or orders for this customer. ([HYPERLINK \ "Figure4"]({ HYPERLINK \ "Figure4" }))

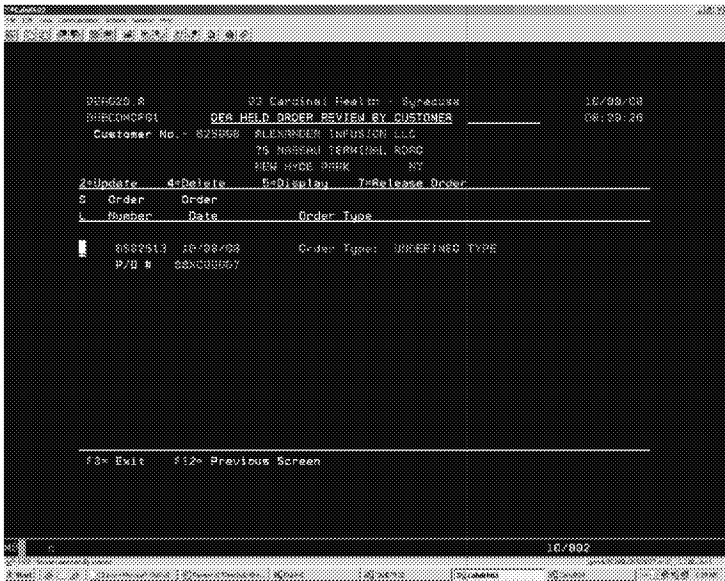


Figure [SEQ Figure * ARABIC]({ SEQ Figure * ARABIC })

To view the held order enter 5 (Display) on the line in front of the order to be viewed ([HYPERLINK \ "Figure4"]({ HYPERLINK \ "Figure4" })), press enter.

A new screen opens listing the held contents of the order. ([HYPERLINK \ "Figure5"]({ HYPERLINK \ "Figure5" }))



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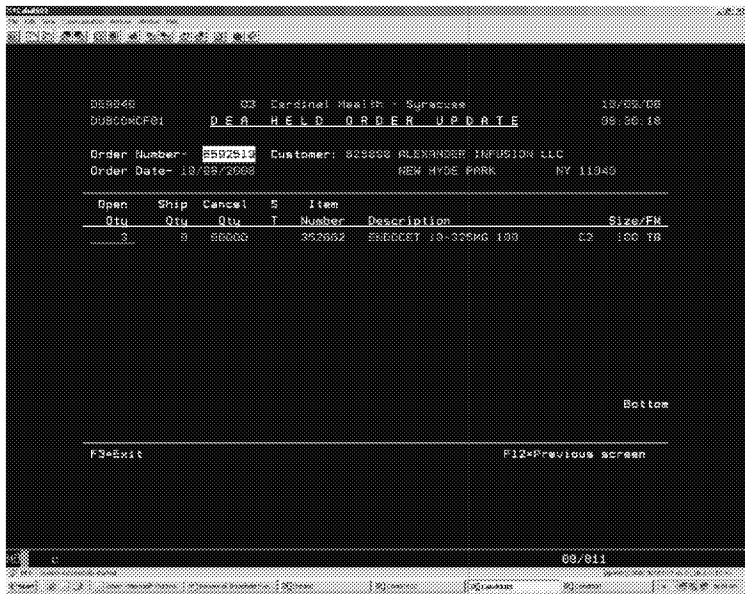


Figure [SEQ Figure * ARABIC]({ SEQ Figure * ARABIC })

4.2.3 Review Customer’s order in Distrack for:

- 1. Type of drug family products in held order.
- 2. Quantity of drug family products in held order.
- 3. Reasonableness of total drug family order.

4.2.4 Decision point questions: (made by an individual degreed in pharmacy)

- 1. Is the order reasonable based upon **applied reasoning** (e.g. seasonal events; natural events; end of month order; a shortage of other products; regional prescribing habits; the location of pharmacy or facility in relation to health care providers; and/or incorrect monthly limit)?
- 2. Is the order excessive (e.g. order entry error, duplication)?
- 3. Is the order suspicious (excessive in quantity, strength, frequency, unexplainable deviation from the norm)? (If deemed suspicious see [[HYPERLINK "http://internal.mps.cardinal.net/teams/gradocs/usdistribution/SOPs/HSCSQRA/OP/HSCSQRA-OP-P014.doc"](http://internal.mps.cardinal.net/teams/gradocs/usdistribution/SOPs/HSCSQRA/OP/HSCSQRA-OP-P014.doc)]({ [HYPERLINK "http://internal.mps.cardinal.net/teams/gradocs/usdistribution/SOPs/HSCSQRA/OP/HSCSQRA-OP-P014.doc"](http://internal.mps.cardinal.net/teams/gradocs/usdistribution/SOPs/HSCSQRA/OP/HSCSQRA-OP-P014.doc) })

After viewing the order press F12 to return to the list of held orders ([[HYPERLINK \ "Figure4"](#)]({ [HYPERLINK \ "Figure4"](#) })

4.2.5 Once decision is made:

- 1. Order deemed reasonable:
 - i. Release held order in Distrack.

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- ii. Increase monthly threshold in Distrack. (if appropriate)
 - a. Any threshold adjustments in Distrack must have rationale recorded and require a site visit to the customer
 - b. Once a decision in Distrack is made, the following screen appears ([\[HYPERLINK \ "Figure6" \]](#) [\[HYPERLINK \ "Figure6" \]](#))

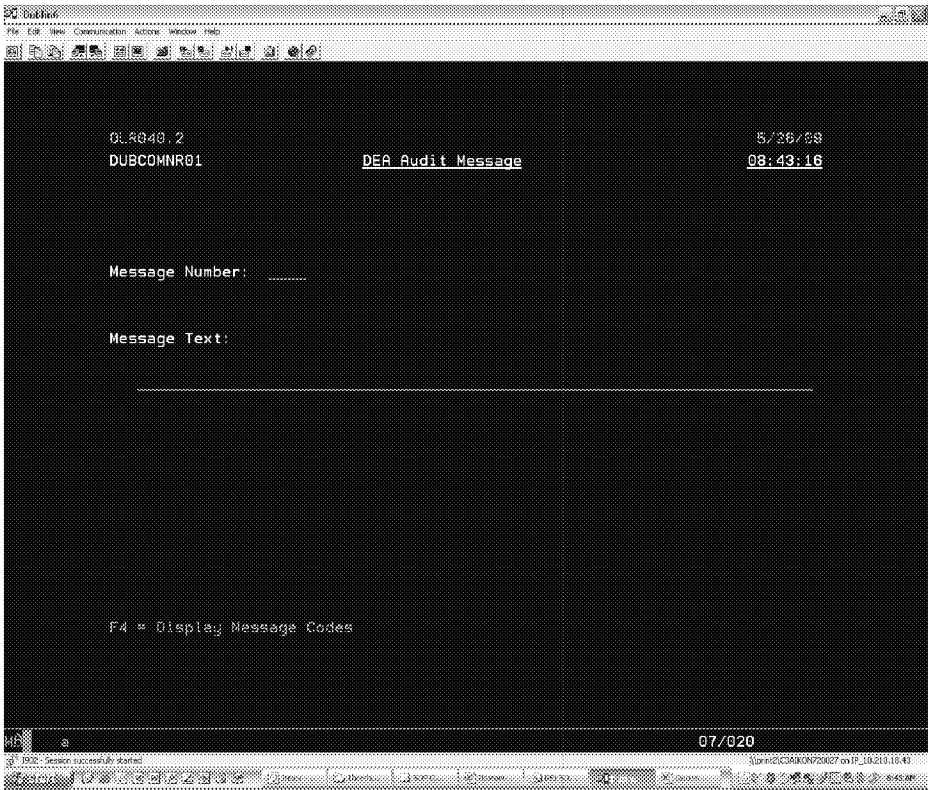


Figure 6

- c) The user has the choice of selecting one of the pre-formatted responses ([\[HYPERLINK \ "Figure7" \]](#) [\[HYPERLINK \ "Figure7" \]](#)) or input their own response ([\[HYPERLINK \ "Figure8" \]](#) [\[HYPERLINK \ "Figure8" \]](#))

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Figure 7

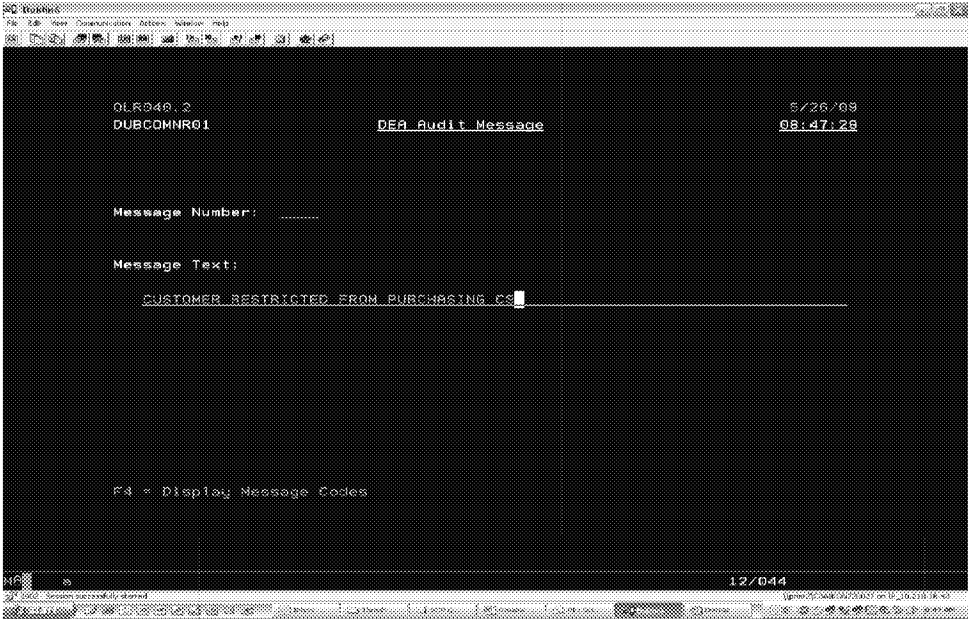


Figure 8

- iii. Document decision on the Customer Anti-Diversion Profile.
- iv. Disseminate QRA decision through SOM web-site.

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2. Order deemed unreasonable:

i. Order entry error:

1. Cut order in Distrack.
2. Adjust accrual limiter in Distrack.
3. Document decision on the Customer Anti-Diversion Profile.
4. Disseminate QRA decision through SOM web-site.

ii. Suspicious order:

1. Cut order in Distrack.
2. No accrual limiter adjustment.
3. Document decision on the Customer Anti-Diversion Profile.
4. Disseminate QRA decision through SOM web-site.
5. Report suspicious order per policy.

4.2.6 Releasing the held order is accomplished from the list of held orders screen. ([
HYPERLINK \l "Figure4"]{HYPERLINK \l "Figure4" })

To release the held order enter 7 (Release Order) on the line in front of the order to be released, press enter.

The order is released.

4.2.7 Deleting the held order is also accomplished from the list of held orders screen. ([
HYPERLINK \l "Figure4"]{HYPERLINK \l "Figure4" })

To delete the held order enter 4 (Delete) on the line in front of the order to be deleted, press enter.

Pressing enter opens the next screen which lists the contents of the held order. ([HYPERLINK \l "Figure9"]{HYPERLINK \l "Figure9" })

Enter 4 (Delete) in front of the product to delete it from the order. If more than one product is being held, select the products to be deleted, if the whole list of products needs deletion place a 4 in front of each item and press enter until all the product lines are deleted.

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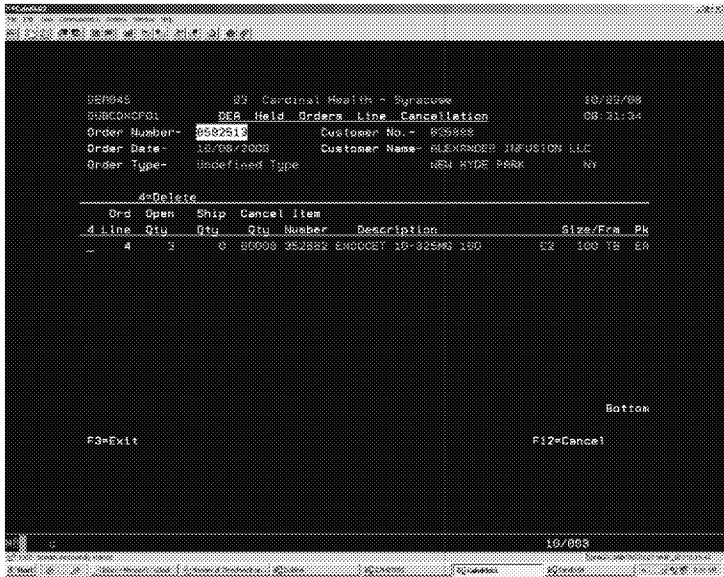


Figure 9

4.2.8 Adjusting monthly limiter in Distrack;

Adjusting a customer’s threshold level and/or accruals in Distrack is always done through the Dublin 6, Aurora distribution center area. ([HYPERLINK \V "Figure1"] [{ HYPERLINK \V "Figure1" }])

- On the initial opening screen in Dublin 6, type AR in the space next to the Option line and Press enter.

The DEA Operations Menu opens. ([HYPERLINK \V "Figure10"] [{HYPERLINK \V "Figure10"}])



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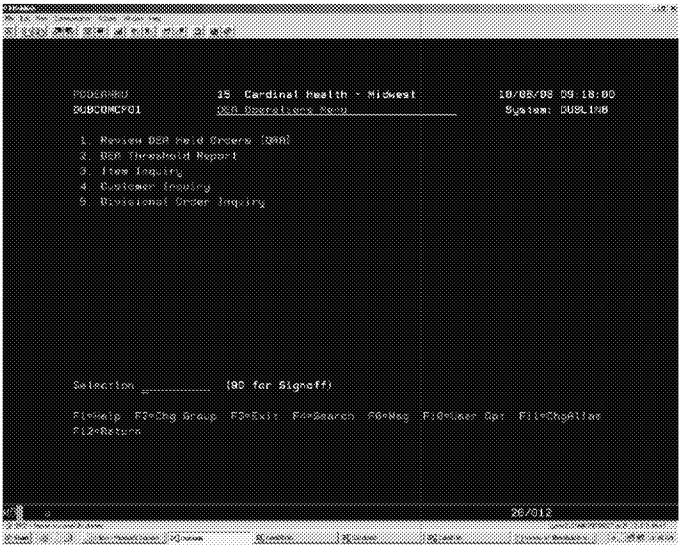


Figure 10

Press the F10 key.

The Class File Maintenance Box Opens. ([HYPERLINK \ "Figure11"]){HYPERLINK \ "Figure11"}



Figure 11

In the Selection blank type 1. (Limit by Class File Maintenance Program)

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Press Enter.

The Threshold Limit Maintenance Screen opens. ([HYPERLINK \l "Figure12"]{ HYPERLINK \l "Figure12" })

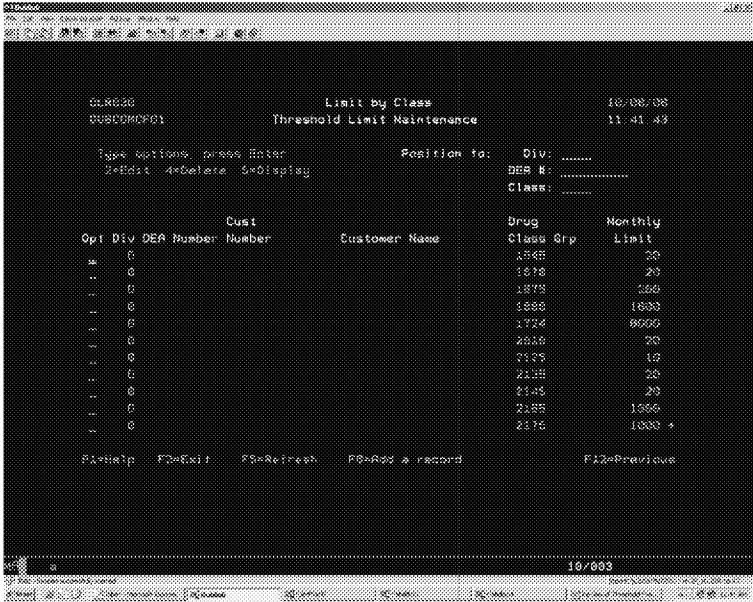


Figure 12

To view or adjust a customer's threshold or accrual information in the Position to field located at the top right of the screen type the customer's distribution center's division number, the customer's DEA number, and drug family class number ([HYPERLINK \l "Figure13"]{ HYPERLINK \l "Figure13" })

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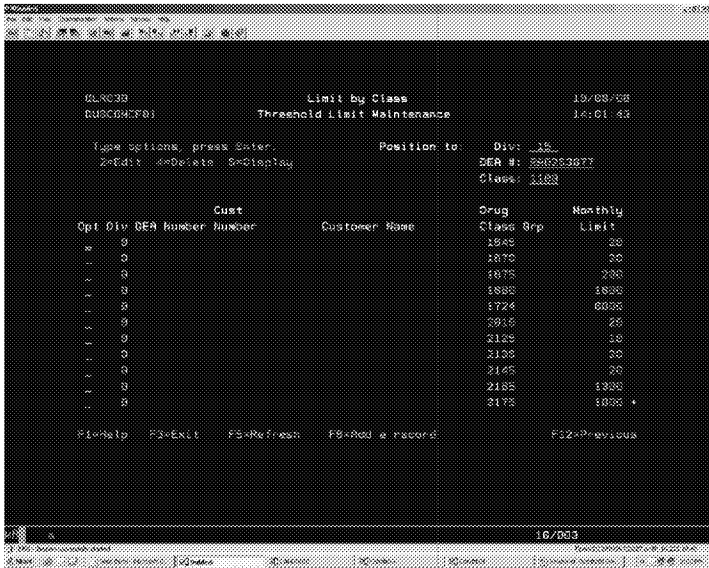


Figure 13

Press enter.

The customer's list of drug class families and monthly limits opens. ([HYPERLINK \ "Figure14"] [HYPERLINK \ "Figure14"])

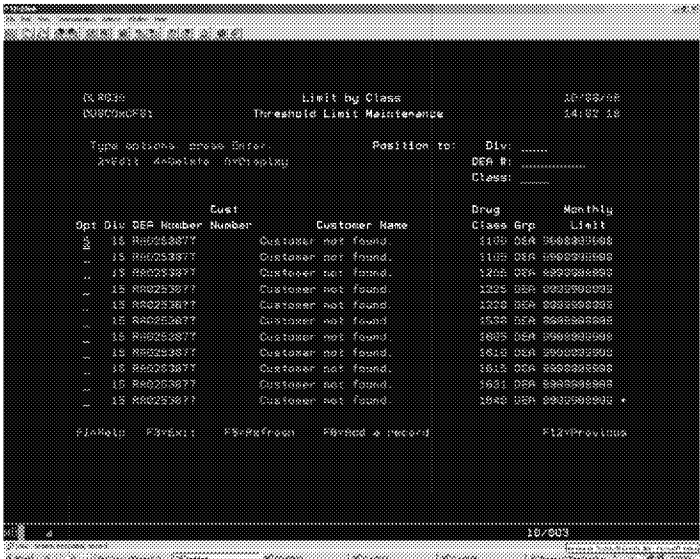


Figure [SEQ Figure * ARABIC] [SEQ Figure * ARABIC]4

Placing a 5 (Display) on the line in front of the drug class and pressing enter allows viewing the customer's information for that specific drug family. ([

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~~HYPERLINK \l "Figure15"]{HYPERLINK \l "Figure15" })~~

This screen also shows the last date the customer's threshold was adjusted. No changes can be made from this view. Press F12 to return to the previous screen.

[illegible]

Figure 15

Placing a 2 (Edit) on the line in front of the drug class and pressing enter opens the screen for editing the customer's information for that specific drug family.

([\[HYPERLINK \l "Figure16"\]{HYPERLINK \l "Figure16"}\]](#)) and ([\[HYPERLINK \l "Figure17"\] {HYPERLINK \l "Figure17"}\]](#))

The edit screen ([\[HYPERLINK \l "Figure17"\]](#) ~~{[HYPERLINK \l "Figure17"]}~~) allows a customer's monthly limit (threshold) to be adjusted, the limit reached flag to be removed (or entered), and the customer's total monthly accruals to be adjusted. After adjustments are completed pressing enter returns to the original customer's drug family limits screen. The threshold change will appear with return to this screen.

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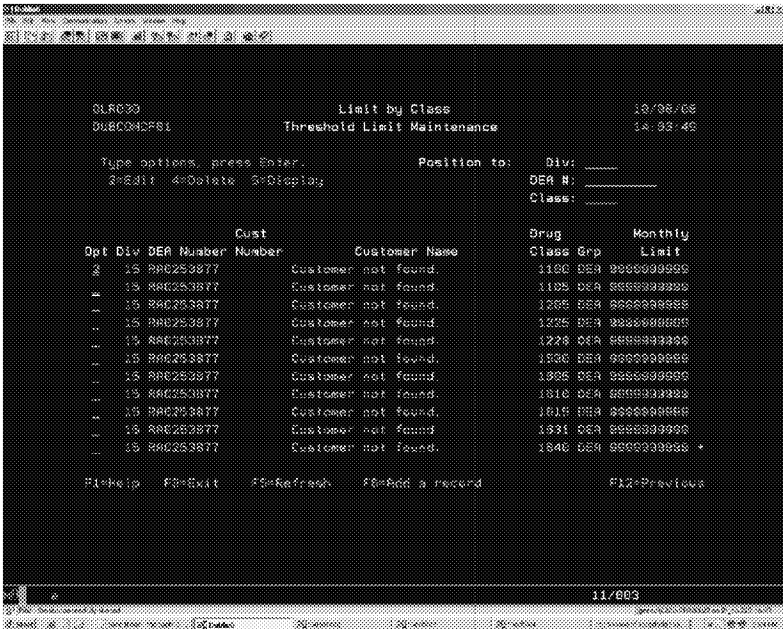


Figure [SEQ Figure * ARABIC] [{ SEQ Figure * ARABIC } 6



Figure [SEQ Figure * ARABIC] [{ SEQ Figure * ARABIC } 7

4.2.9 After QRA completes review of the customer’s order(s), releases or deletes the customer’s order(s) and adjusts the customer’s threshold (if appropriate) this information is documented and disseminated using the SOM web-site.

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Dissemination of QRA decision through SOM web-site

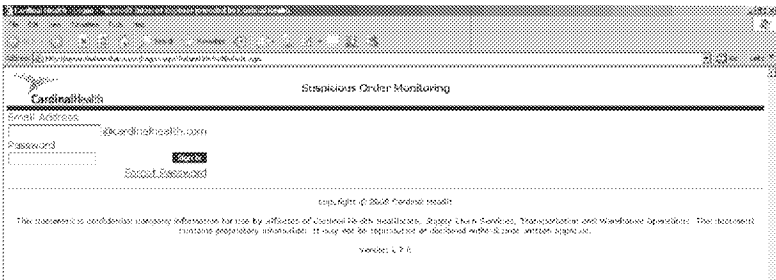


Figure [SEQ Figure * ARABIC] [SEQ Figure * ARABIC]8

Sign onto the SOM web-site using the above screen. ([HYPERLINK \ "Figure18"] [HYPERLINK \ "Figure18"])

The web-site opens the initial work request screen. ([HYPERLINK \ "Figure19"] [HYPERLINK \ "Figure19"])

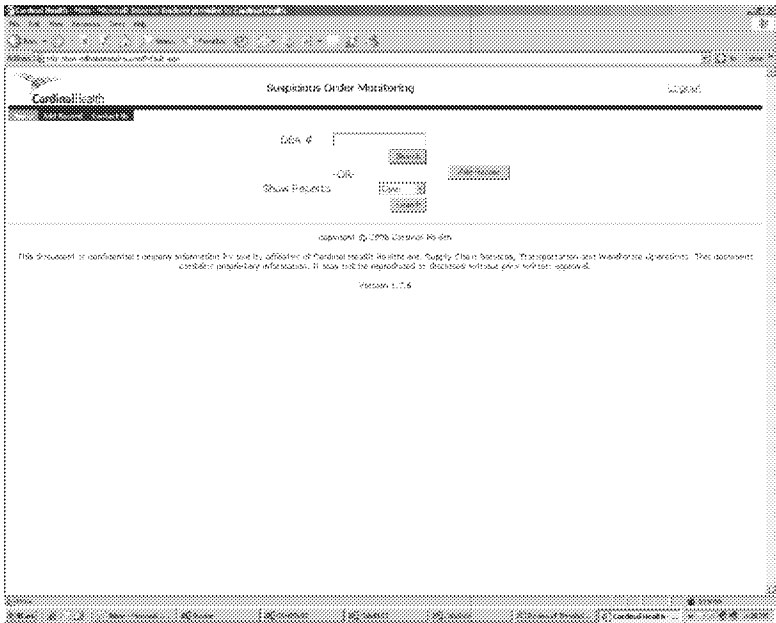


Figure 19

Typing the customer's DEA number at the DEA# prompt displays all the threshold events under the customer's DEA number. (open, closed, and site visit)

Selecting "Show Reports" by clicking on the "Search" button displays the screen with all "open" reports. (using the drop down menu allows viewing of reports under different file types) ([HYPERLINK \ "Figure20"] [HYPERLINK \ "Figure20"])



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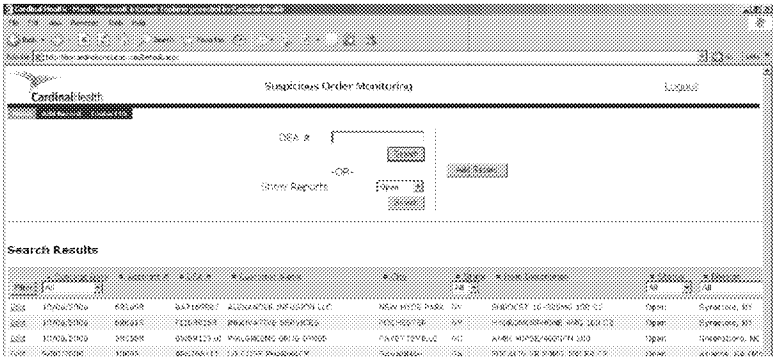


Figure 20

Clicking on the “edit” in front of a customer opens the threshold event documentation and communication window. ([HYPERLINK \ "Figure21"]{-HYPERLINK \ "Figure21" })

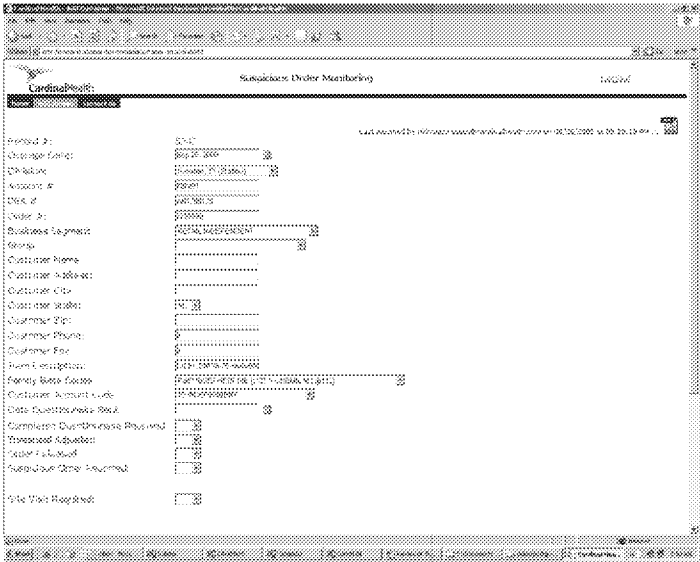


Figure 21

To complete the SOM reporting use the drop down boxes under the following categories to communicate and document the customer's threshold event status.

Completed Questionnaire Received (Yes/No) changed to “Yes” when threshold event questionnaire is received at QRA. ([HYPERLINK \ "Figure22"]{-HYPERLINK \ "Figure22" })

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Figure 22

Threshold Adjusted (Yes/No) changed when threshold changed in Distrack. ([
HYPERLINK \1 "Figure23"] { HYPERLINK \1 "Figure23" })

Figure 23

Order Released (Yes/No) changed to reflect decision to ship product to customer. ([
HYPERLINK \1 "Figure24"] { HYPERLINK \1 "Figure24" })

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Figure 24

Suspicious Order (Yes/No) changed to Yes creates a drop down box requesting a date this suspicious order is reported to the DEA. ([HYPERLINK \1 "Figure25"](#) [HYPERLINK \1 "Figure25"](#) } and [HYPERLINK \1 "Figure26"](#) [HYPERLINK \1 "Figure26"](#) }

Figure 25

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Figure 26

Site Visit Required (Yes/No) changed to Yes creates a drop down box requesting a site visit by either the PBM (Sales) or QRA, a drop down box as to whether the visit has been scheduled and a drop down box requesting when the site visit was completed. ([HYPERLINK \l "Figure27"] { HYPERLINK \l "Figure27" }) and [HYPERLINK \l "Figure28"] { HYPERLINK \l "Figure28" })

Figure 27

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Figure 28

Status (Open/Closed/Site Visit/Archive) changed to closed when SOM completed, changed to Site Visit if a site visit is required, and Archive. (for future use) ([HYPERLINK \1 "Figure29"] {HYPERLINK \1 "Figure29" })

Figure 29

Status Justification (several choices including Other) to disseminate QRA's

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reasoning and conclusions about the customer's threshold event order. If other is chosen the free form field Justification Comments should be used for the explanation. ([HYPERLINK \ \ "Figure30"]{HYPERLINK \ \ "Figure30" })

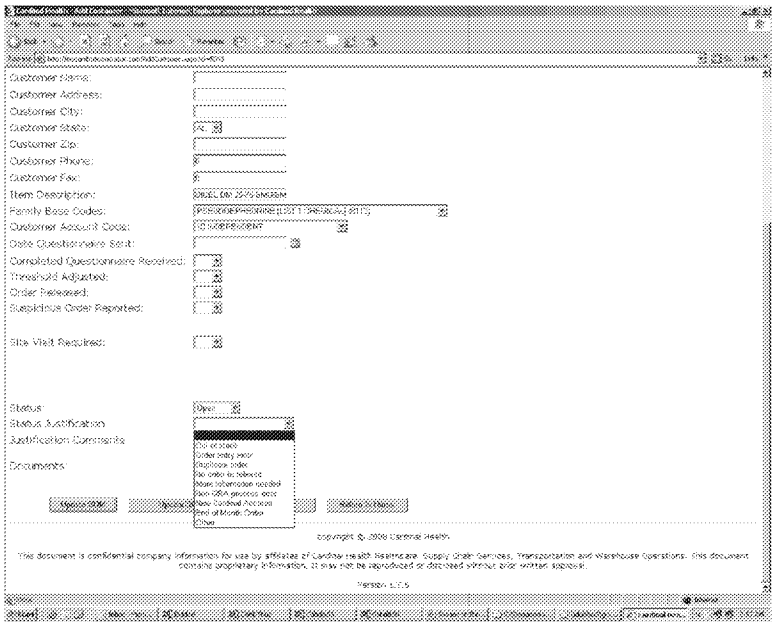


Figure 30

4.2.10 To accept/update and send threshold information select “Update SOM” at the bottom of the screen. Once screen refreshes then select “Return Home” at the bottom of the screen.

The screen returns to opening screen. (Note: Failure to update the SOM prior to returning home cancels all status changes and the SOM remains unchanged)

4.2.11 The customer's threshold event has now been completed and documented in both Distrack and the SOM web-site.

5.0 APPLICABLE DOCUMENTS

[HYPERLINK "http://internal.mps.cardinal.net/teams/qradocs/usdistribution/SOPs/HSCSQRA/CAD/HSCSQRA-CAD-C001.doc"]{HYPERLINK "http://internal.mps.cardinal.net/teams/qradocs/usdistribution/SOPs/HSCSQRA/CAD/HSCSQRA-CAD-C001.doc"}

Process For Daily Threshold Reporting

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Approvals on file in the Pharmaceutical Distribution Document Center			
Approvers: Michael A. Mone		Owner:	Chris Forst
		Doc Center:	Jason Paul Snouffer
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DCN-2457	11/05/09	Updated to conform with current Cardinal Health Pharmaceutical restructuring and updated document number from HSCSQRA-CAD-C007 to PDQRA-CAD-C007.	
DCN-2273	12/22/08	Initial release of new procedure, HSCSQRA-CAD-C007.	

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